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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,295	10/31/2003	Hikmat Hojeibane	CRD-5051	2568

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EXAMINER

PELLEGRINO, BRIAN E

ART UNIT PAPER NUMBER

3738

DATE MAILED: 09/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/699,295

Applicant(s)

HOJEIBANE ET AL.

Examiner

Brian E Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 23,25,26,30 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22,24,27-29,32 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/22/06 has been entered.

Specification

Correction to the Abstract is noted and accepted.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the new limitation in claims 1,32,33 that the first end of the connecting member is "rigidly attached" to the second end of the anchor and its second end being "rigidly" attached to the proximal collar was not found in the written disclosure.

Additionally, there is no description of the "cantilever valve strut being free to deflect in a radial direction from the longitudinal axis" in the specification to explain what is meant by this limitation.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5,8,9,22,24,27-29,32,33 are rejected under 35 U.S.C. 102(e) as being anticipated by Huter et al. (6511496). Fig. 1 shows a prosthetic valve having an anchor structure (tubular stent) on a balloon, which is attached to a catheter device that has a collar **40** proximal to the anchor. It is well known in the art that stents have first and second open ends. The collar is attached to a cantilever strut assembly **24** which has a membrane assembly **22** attached thereto that has a first open end and a second closed end. Huter discloses the structural frame may be made of metals or polymers, col. 4, lines 2-4. The membrane is made of synthetic material, col. 7, lines 45-49. Both the connecting member and the cantilever strut are "substantially straight". The use of "substantially constant diameter" or "substantially conical shape" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and relatively unlimited. It can be construed that element 26 can be a centering leg and provides means for indirectly and directly attaching the assembly. It can be construed that the connecting member or element **26** is *indirectly* attached to the collar **40** and provides a rigid attachment which is joined with the valve assembly and struts

restrained in a sheath and a catheter having a balloon secured thereon with a compressed stent that can be construed to be rigidly restrained since it is compressed. Fig. 2 shows the cantilever valve struts expanding radially and thus can be considered to be "free to deflect".

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huter et al. '496 in view of Konya et al. (6368338). Huter et al. is explained supra. However, Huter fails to disclose the membrane material comprises a reinforcement fiber. Konya shows (Fig. 1) a filtering device. Konya also teaches that the filtering device can include reinforcement or structural fibers, col. 12, lines 23-31. It would have been obvious to one of ordinary skill in the art to use reinforcement fibers as taught by Konya with the membrane of Huter such that it strengthens the apparatus and prevents collapse.

Claims 6 and 7 rejected under 35 U.S.C. 103(a) as being unpatentable over Huter et al. '496 in view of Quijano et al. (5500014). Huter is explained supra. However, Huter does not disclose the use of biological vein material for the membrane. Quijano et al. teach that venous graft material is used in prosthetic valve devices (col. 6, lines 6,7) and that tanning the material provides certain stiffness properties, col. 11, lines 22-25. It would have been obvious to one of ordinary skill in the art to use venous material as taught by Quijano et al. for the membrane of Huter et al. such that it provides a

natural biological material that is sufficient to withstand the pressure of the blood flow in the patient since it is a natural material.

Claims 10,12-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huter et al. '496 in view of Alt et al. (5788979). Huter et al. is explained as before. However, Huter fails to disclose the structural frame or the membrane is coated with a therapeutic agent. Alt et al. teach that biodegradable polymer materials can be loaded with drugs or pharmaceutical agents (col. 4, lines 14-29) to treat an area where a prosthesis (col. 8, lines 57-60) is implanted. It would have been obvious to one of ordinary skill in the art to use a biodegradable polymer with a drug as taught by Huter et al. with the device of Alt et al. such that it prevents restenosis or thrombosis from occurring.

Response to Arguments

Applicant's arguments filed 5/25/06 have been fully considered but they are not persuasive. Applicant argues that Huter fails to disclose a closed end valve and that Huter's device is an embolic filter not a valve. However, it is known that filters are closed or trap particles as admitted by Applicant on page 11 of the amendment. Since the filter of Huter traps objects it can be construed to be closed and is as much of a valve as Applicant's claimed closed valve. Applicant also argues that Huter does not disclose anchor structure and states that the structure on the catheter could be ribs. This is not persuasive. The structure illustrated on the balloon of Huter's device is clearly intended to be a stent or "anchor structure" as is well known in the art. See US

6375676 which clearly shows similar structure naming it a stent or anchor structure.

Applicant argues the anchor structure of Huter is not “rigidly” attached to the connecting member. However, the specification fails to describe what is meant by the new limitation. If element (26) of Huter is interpreted as a “connecting member” it can be construed that since it is attached to the collar (40) at one end of the struts, it is indirectly affixed in a rigid fashion. The strut assembly can also be interpreted to be “rigidly” restrained via the sheath (18) that is compressed with the balloon and anchor structure in a rigid fashion and then is expanded once the balloon is inflated. Applicant additionally argues that Huter does not disclose a “connecting member,” but fails to describe how Applicant’s “connecting member” is structurally different. Claims are to be interpreted in their broadest reasonable sense and since there is no structure to define the claimed “connecting member” it can be interpreted that Huter’s apparatus (26) acts as a connecting member and indirectly or directly connects with the struts and anchor structure. Applicant also argues that Huter does not disclose cantilever valve struts that are free to deflect radially. However, this is not described in the specification to define this new limitation. It can be construed that since the structure of Huter is not a solid tube and are elongate thin members forming struts as Applicant’s struts, the struts of Huter are “free to deflect” and are cantilever type struts.

In response to applicant’s argument that Konya does not disclose a “reinforcement fiber” as claimed, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious.

See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The fibers disclosed by Konya clearly function as "reinforcing" of the strut member, see Fig. 11. Thus, the rejection of Huter in view of Konya is proper. The other combination of references are also obvious expedients to the Huter device and thus are proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Th (6:30am-4pm) and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

